REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claim 18 was cancelled previously. Claims 1, 19, 37 and 57 have been amended to replace the transitional phrase "consisting essentially of" with "comprising", with support for this amendment found in the original claims.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-17 and 19-57 will be pending, with claims 27 and 31-36 withdrawn from examination.

II. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1-17, 19-26, 28-30 and 37-57 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over U.S. Patent No. 6,287,596 to Murakami et al. ("Murakami"). Applicants respectfully traverse the rejection.

(i) The rejection is based on improper reliance on inherency.

The Examiner asserts that Murakami reads on the claim limitations of at least one active agent and pullulan. Nevertheless, Murakami fails to teach or suggest the concentration of pullulan or the friability of the composition. To bridge the gap between the claimed invention and the cited art, the Examiner asserts that "[f]riability is a property of the product" (Office Action, page 3, lines 1-3, 7, 9 and 11).

It appears that the Examiner invoked "inherency" to substantiate the rejection. Pursuant to MPEP 2112, the Examiner bears an initial burden to establish proper reliance on inherency. The claimed solid dosage form comprises at least one active agent and pullulan having a

concentration of about 99.9% to about 0.1% (w/w). In contrast, both the active agent and pullulan are optional ingredients in the prior-art composition. More specifically, Murakami teaches a quickly disintegratable compression-molded material comprising an excipient and erythritol (abstract and column 4, lines 18-20). Murakami's material may optionally comprise a pharmaceutically active ingredient (1-70% by weight) or an additive, such as a binding agent, *e.g.*, pullulan (unknown amount). *See* column 5, lines 54-60 ("No particular limitation is imposed on the pharmaceutically active ingredients which may be used in the present invention..."), and column 7, lines 6-12 and 28. Thus, the Examiner has failed to establish "inherency" in the absence of any proof that the claimed solid dosage form comprising at least one active agent and pullulan at a concentration of about 99.9% to about 0.1% is readily available in view of the teachings of Murakami.

Pursuant to MPEP 2112,

> [t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)...Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient...In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art..."

(citations omitted). Thus, the Examiner has yet to prove that Murakami's material ***necessarily*** (i.e., ***inevitably***) possesses a friability of less than about 1%, as prescribed by claim 1.

The Examiner contends that "it is also noted that friability is a property of the dosage form and applicant has not factually shown that the dosage of Murakami is not friable" (Office Action, page 5, lines 7-9). However, in view of the discussion above, the Examiner has failed to

properly establish "inherency" and therefore, the burden remains with the Examiner to substantiate the "inherency" rationale.

(ii) The reason to select the specific elements to obtain the claimed dosage form is lacking.

As discussed *supra*, the claimed solid dosage form requires the specific combination of at least one active agent and pullulan, both of which are optional ingredients in the prior-art composition.

This claimed specific combination of active agent and pullulan is not disclosed or suggested by Murakami. For instance, Murakami discloses that inclusion of a pharmaceutically active agent is optional (see column 5, lines 54-60). Murakami also describes "a variety of additives" that may be optionally included in the composition.

To arrive at the claimed invention, one skilled in the art has to first include the optional ingredients, an active agent and an additive, select a binding agent out of 10 disclosed categories of additives, and then select pullulan out of 14 exemplary binding agents. The particular combination of elements required by the present claims was selected by the inventors from numerous choices of pharmaceutical additives. In the absence of any guidance from the cited art, the Examiner has fallen into the trap of hindsight distortion, *i.e.*, breaking the claims down to their component elements, searching for each element in the prior art, and then putting the elements back together using Applicants' claims as a road map. As such, the rejection rationale is only by the improper reliance on this impermissible hindsight that the Examiner identified the specific elements in the references and formulated the combination of the elements as necessary to obtain the claimed composition. *See Ortho-McNeil Pharmaceutical Inc., v. Mylan* (Fed. Cir. 2008) at 10 ("[i]n other words, Mylan's expert, Dr. Anderson, simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious. Of course this reasoning is always inappropriate for an obviousness test based on the language of Title 35…").

In fact, Murakami has no mention of friability. Thus, it is impossible for one skilled in the art to select for the required elements of the claimed product to obtain a dosage form having a friability of less than about 1%, because the criteria of friability was not disclosed in the cited art. Noticeably, Murakami discusses the "hardness" of the obtained material (see column 9, line 62, through column 10, line 5). However, "hardness" and "friability" are two different parameters in determining the mechanical strength of a solid dosage form, with no necessary correlation with each other. Thus, the disclosed "hardness" fails to render the claimed invention obvious.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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